K122074

510(k) SUMMARY

OCT 12 2012

iFuse Implant System®

510(k) Owner's Name, Address, and Telephone Number
SI-BONE, Inc.
3055 Olin Avenue, Suite 2200
San Jose, CA 95128
(408) 207-0700

Contact Person
Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services LLC
Regulatory Consultant to SI-BONE, Inc.
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Date Prepared: July 5, 2012

Trade Name of Device: iFuse Implant System®

Common or Usual Name: Orthopedic Rod

Classification Name:
21 C.F.R. 888.3040 – Smooth or threaded metallic bone fastener; Product Code OUR

Predicate Devices: SI Joint Fusion System by SI-BONE, Inc. (K080398, K092375 and K110838)

Intended Use
The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Device Description
The iFuse Implant System® consists of porous plasma spray coated titanium implants and associated surgical instruments. The iFuse Implant lengths range from 30mm to 70mm in 5mm increments with a diameter of 4.0 and 7.0 mm. The device is classified as smooth or threaded metallic bone fixation fasteners as Class II devices pursuant to 21 C.F.R. § 888.3040. The fusion rods are implanted using the same instrumentation previously described in K080398, K092375 and K110838.

Technological Characteristics
The SI Fusion System consists of a series of metallic (titanium), porous plasma spray coated rods, intended for surgical implant within the bone to create fixation. The system includes 4.0 mm and 7.0 mm diameter fusion rods, which range in length from 30 mm to 70 mm.

Performance Data
No performance testing was required to support the modified labeling that is the subject of the 510(k).

Substantial Equivalence
The iFuse Implant System has the same intended use, indications for use, and technological characteristics as the predicate device. Thus, the iFuse Implant System is substantially equivalent to its predicate device.

Conclusions
The iFuse Implant System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2012

SI-Bone, Incorporated
% Domecus Consulting Services, LLC
Ms. Cindy Domecus
Principal
3055 Olin Avenue, Suite 2200
San Jose, California 95128

Re: K122074
Trade/Device Name: iFuse Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: July 9, 2012
Received: July 16, 2012

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SI-BONE iFuse Implant System

Indications for Use:

The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122074